The SOURCE

DECEMBER/JANUARY 2001/2002

THE NEWSMAGAZINE OF THE PLASMA COLLECTION AND FRACTIONATION INDUSTRY

ABRA/PPTA Merger

Looking Back: Looking Forward

An Interview with Congresswoman Hilda Solis

Roland Reiner Retires

Dr. Roland Reiner (center) was a member of the management team of Biotest Pharma GmbH and of the Executive Board of Biotest AG. Dr. Reiner received an award from PPTA Europe president Jean-Marie Vlassembrouck (right) recognising his long service to PPTA and marking his retirement as a Board member of PPTA Europe, a post he has filled since 1995. Charles Waller, Executive Director for PPTA Europe is at left.

PPTA
Plasma Protein Therapeutics Association

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The mission of PPTA is to provide leadership in areas of plasma therapies, donor recruitment and education, national health policy, quality and safety standards and by supporting collaboration among plasma organizations in enhancing patient health.

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In My View

With One Voice

Jan M. Bult
President PPTA

With the advent of every new year, come promises of new resolutions and renewed commitments. This is true both personally and professionally. It seems appropriate, then, that our New Year Issue of the *SOURCE* magazine, carries as the lead story the merger of the Plasma Protein Therapeutics Association (PPTA) and ABRA. For this merger brings with it a renewed promise and commitment to all of our stakeholders. We will now truly speak with one voice for the plasma collection and fractionation industry and the consumers we serve around the world. It is a reaffirmation to continuous improvement for our industry and members.

The strength of our new organization comes not merely in numbers but in a focused approach to service, to a streamlined approach to quality management and to a global view of the industry. Our organization is grounded in the combination of the experience of ABRA (30 years) and PPTA (10 years). These experiences of the 2 professional organizations have become visible through quality standard setting and innovative services and programs.

… this merger brings with it a renewed promise and commitment to all of our stakeholders. We will now truly speak with one voice for the plasma collection and fractionation industry and the consumers we serve around the world.

In many ways, this new partnership reflects the industry as a whole. Around the globe, companies are coming together to assure the maintenance and management of quality processes from source to therapy.

One of the concerns that often arises when two organizations join together is how to ensure that the interests of both organizations are represented. Throughout the discussions and activities surrounding the merger, the PPTA and ABRA Boards of Directors have worked very diligently to make certain that this will happen.

As we begin 2002, in a world when so much is unpredictable, let one thing be certain: PPTA brings a renewed commitment to patients, regulators and our members that we will continue to provide quality service and a sound public health policy worldwide in the years to come. ●

The SOURCE
THE NEWSMAGAZINE OF THE PLASMA COLLECTION AND FRACTIONATION INDUSTRY
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The PPTA/ABRA Merger

A New Look: An Established Mission

By Christopher P. Healey, President, ABRA

Last year at this time talk of a PPTA-ABRA merger was nothing more than a faint whisper. Now, except for the printing of new letterhead and a few legal formalities, the merger is complete. This change, monumental in so many respects and insignificant in many others, reflects the rapid pace of change throughout the industry. It is clear that our industry is changing at a break-neck speed and to maintain service to our membership, so too, must the Association. Our challenge, of course, is to reinvent the organization while holding on to all that we have worked so hard to establish over the past years.

Since serious talks of merger began, the staff of both Associations and key members of industry have been examining ways the two organizations can function more efficiently and effectively. While the mission of each organization my be stated slightly differently, the common threads that bind the organizations include quality standards, advocacy and consumer outreach. Not surprisingly, it is in these areas that all our stakeholders stand to benefit most from the merger. The new organization can now bring its combined resources to bear on issues that affect patient access to therapies, the development of robust quality and safety standards, and even better collaboration with consumers on issues of common interest.

Our new organization means that the plasma industry can truly speak to the world with one voice. Historically, PPTA has executed the mission of the world's major fractionators. ABRA has given voice to those who collect plasma as a starting material and, equally important, test kit manufacturers, soft-goods suppliers, and other critical support services. The ABRA membership has also expanded to include smaller cutting-edge biotech companies that are exploring new plasma-derived therapies and applications.

More recently, a group of European plasma collection organizations embraced Association membership. Independent and fractionator-owned plasma collection centers in Europe have come to recognized the benefits of col-

Merger ...

laborating with industry partners on issues that broadly impact the industry. They will contribute to the global mandate that has been more recently adopted by ABRA and has long been the hallmark of PPTA.

With this global scope and diversity of membership, our industry can now truly speak to the world with one voice. With the merger complete, ABRA will formally take the name PPTA and become a division under the PPTA umbrella. A new Board of Directors will be empanelled and the stage will be set for a new era of standards setting and advocacy on starting material issues. For PPTA's part, little will change in the daily operations of the organization. But with a renewed global perspective and a diversity of membership, the newly-merged organization will have a wealth of resources to draw upon to the benefit of all stakeholders. ●

Looking Back: Looking Forward

By Joseph Rosen, Chairman, ABRA Board of Directors, President, Sera-Tec Biologicals

ABRA was the first plasma industry trade group and it was originally formed in response to a 1971 proposed Food and Drug Administration (FDA) labeling regulation. During the last 30 years, ABRA has grown in membership to represent almost every source plasma collector in the industry and every major fractionator. Through ABRA's many programs and activities, the private sector plasma industry has changed dra-

Continued on page 26)

QSEAL

Late last year, in Washington, DC, the first five PPTA members received certification through the QSEAL (Quality Standards of Excellence, Assurance, and Leadership) Program. Congresswoman Hilda L. Solis hosted the event and presented the awards to representatives from Alpha Therapeutic Corporation, Aventis Behring, Baxter BioScience, Bayer Corporation and Biotest Pharma.

Representatives from consumer organizations also took part in the presentation and they were: Miriam O'Day from the Alpha-1 Foundation (see following), Marcia Boyle from the Immune Deficiency Foundation and Jan Hamilton from the Hemophilia Federation of America.

The following comments were offered at the ceremony on Capitol Hill and afterward, Congresswoman Solis was interviewed by *The Source* Magazine. ●

Miriam O'Day (left) at a recent QSEAL presentation in Washington, D.C.

A Positive Initiative

Alpha-1 Foundation Comments on QSEAL

Both John Walsh, President and CEO of the Alpha-1 Foundation and Miriam O'Day, Senior Director for Public Policy for the Alpha-1 Foundation, spoke recently on the value and importance of the QSEAL Program to patients who depend on plasma protein therapeutics worldwide. Here are their words:

John W. Walsh: "I am impressed that the plasma fractionation companies, as an industry, have introduced a Quality Certification program with the use of an independent program audit. Improved donor screening and collection and the use of NAT technology are several ways the industry has reassured me as a consumer, that the medication I rely on weekly is being made using rigorous standards."

Miriam O'Day: "On behalf of the Alpha-1 Foundation and individuals affected with Alpha-1 Antitrypsin Deficiency, we are pleased to join Congresswoman Hilda L. Solis to congratulate the five companies represented here today on achieving QSEAL certification. Alpha-1 is a genetic disorder that results in devastating and fatal lung and liver disease. The pulmonary destruction associated with Alpha-1 causes suffering and pain known only to those unable to catch their breath. The only treatment available for the lung disease associated with Alpha-1 (aside from end-stage lung transplantation) is the plasma-derived augmentation therapy which must be infused weekly and is in critically short supply. This therapy may extend the life of the individual for as much as 20 years and may sustain them while they await transplantation. Blood safety and availability are top priorities for the Alpha-1 Foundation and we are pleased to see the industry making efforts to extend their regulatory obligations and employ more rigorous safety initiatives. In addition, the use of an independent audit impresses us as an additional reason to offer our congratulations to those companies receiving QSEAL certification. This is a positive initiative that standardizes procedures and improves consumer confidence." ●

A *Source* Interview:

Hilda Solis

Congresswoman Hilda L. Solis was elected by an overwhelming majority to the 31st Congressional District of California in November of 2000. This district includes parts of East Los Angeles and the cities of El Monte, Azusa, Irwindale, Baldwin Park and more. Congresswoman Solis graduated from California Polytechnic University in 1979 and earned a Masters Degree in Public Administration from the University of Southern California in 1981. During the Carter Administration, she served in the White House Office of Hispanic Affairs and later was appointed management analyst with the Office of Management and Budget in the Civil Rights Division.

She was first elected to public office in 1985 and she served in the California State Assembly from 1992 –1994 and in 1994 she made history by becoming the first Latina ever elected to State Senate. She passed innovative environmental justice legislation aimed at improving low-income and minority communities most affected by pollution and waste. As a result of her innovative leadership in this area she was recognized with the John F. Kennedy Profile in Courage Award. Currently, she serves on the House Education and Workforce Committee and the House Resources Committee. She is a strong advocate for her constituents with her top priorities remain the environment, education and health care.

Recently, Congresswoman Solis hosted a presentation for the first five companies to be certified through the PPTA QSEAL Program. Following this presentation, the SOURCE had an opportunity to sit and talk with her.

Q: What are the primary objectives you hope to achieve as a Congresswoman?

A: I would like to continue my work on issues affecting families – educational issues that can increase opportunities for youth in our district and for those who want to go on to higher education. I want to ensure that our constituents have access to quality health care. A planned universal health care task force forum that we sponsored this year in LA County was a success, and I'd like to see us do that again. We had five members of Congress there: Reps. John Conyers, George Miller, Diane Watson, Barbara Lee, Juanita McDonald and L.A County Supervisor Molina. We did testimony several hours on issues such as access to health care with personal stories shared on how to improve health care and what issues need to be addressed in the future. It was a very eye-opening experience and something that we want to continue this year and perhaps even take on the road.

Health care is one of my three top priorities. Especially with the present recession affecting constituents in our district so dramatically. We have a 7- 9 % unemployment rate in our district and, unfortunately, under the current system, if you are unemployed you have no health care. Small employers can't afford the coverage and it exacerbates the situation. It doesn't mean that we need socialized medicine, but we need better access for all people. In the State Senate, I drafted a bill (SB 480) for a study and more research on the universal health care, which will be released next year. This is a state level study. I am glad that I was a part of that. I will continue to create public and private partnerships to improve access to quality health care services. These issues must be addressed.

... under the current system if you are unemployed you have no health care. Small employers can't afford the coverage and it exacerbates the situation. It doesn't mean that we need socialized medicine, but we need better access for all people.

Congresswoman Solis checks her schedule with her staff.

Reimbursement issues must also be managed and Congress must play an appropriate role in the debate. In California, we have an antiquated formula for reimbursement–not just California, but in other states in the Southwest as well. We must take a serious look at it. We are wasting opportunities to address this issue and protect patient access to health care. We have a strong need to revamp the system as well as provide resources to support demonstration projects and the like. I am hopeful that we can come up with some legislative solutions next session on the reimbursement issue. This will be a challenge given the tight budgetary constraints that Congress is now operating under, but we can rise to the challenge if we work together in a bipartisan manner.

I want to continue to advocate for continuing research into diseases such as diabetes as they affect the most vulnerable populations like those in my district. I am always looking for new opportunities to provide government support and enhance my constituents' quality of life. We need to do a whole slew of things in the area of medical research and I believe working in partnerships will help us achieve those goals. Sadly, many of the kids in my district are below the poverty level and do not receive an appropriate level of services. We need to ask ourselves, "Do we have on-site health care available to everyone?" This is a crucial question. I secured $260,000 in federal funds for a dental clinic near (one of your members) Alpha Therapeutic Corporation's facility. It would provide for increased and improved access to health care and preventative care. We're looking at a wrap-around program that would be lodged in the school. We need to find creative ways to reach these populations. I am always searching for innovative solutions. I'm excited about these projects. It is important to continue to provide support for research. Cervical cancer affects many people who live in poverty, and many of these can be prevented with health care screening and if treated early. We look for support and we need to create more incentives to make these things happen. People realize the importance of maintaining access to health care services and treatments, and this is what the people I serve want to see – that's why they voted for me.

Hilda Solis ...

Q: Are you finding the job more difficult than you imagined? Are there more barriers than you expected to achieving your agenda?

A: It is sometimes very frustrating in my new role of being in the minority party, however, doing the people's work has its rewards. I am proud of the work I do here on behalf of my constituents and I do my best to serve them well. The very fact that I can't even have a bill I authored heard on the floor here is disappointing. I truly believe the public doesn't even understand the magnitude of what being in the minority party here means. These barriers hinder my democratic colleagues and I from fulfilling our mission in Washington–to be the most effective legislators and advocates for our constituents. I'm hopeful the Democratic Party can pick up more House seats in next year's election. The entire congressional structure here is based on the seniority system. In California, we were on a term-limited track and so you could attain a senior committee position in a few years. Here it can take decades–literally. I served in the State majority (in California) for the last eight years. Furthermore, we have limited resources. We can't meet all needs of our constituents and municipalities in this time of recession with the decreasing surpluses and the debt now growing again. I also believe it is still difficult to be a woman legislator.

We've seen many changes here since September 11. It has changed the way we look at issues and at our jobs. I believe we have become more focused.

Q: What has been the most satisfying part of the job to date for you?

A: There are lights of hope; I have successfully sponsored amendment language that prevailed in one of the appropriations bills. Not bad progress for a freshman legislator. But, I have a lot more in mind to do. The adoption of our language has been an important milestone for me and I can see that we are making a difference. Progress in Washington is incremental. Sponsoring a stand-alone bill and shepherding it through the process is a hurdle that I plan to overcome in time. Writing letters on behalf of our constituents to provide solutions for individual problems is a satisfying experience for me and I am grateful that my influence has impacted the release of grant funds in certain situations. Knowing that my constituents see me on C-SPAN and realize and understand that I am working for them on a daily basis is very satisfying. Having the support of so many of my colleagues as a new member is a wonderful thing. We've seen many changes here since September 11. It has changed the way we look at issues and at our jobs. I believe we have become more focused. So I can go home holding my head high.

Q: Medicare reimbursement issues, specifically the Hospital Outpatient Prospective Payment System (HOPPS)–Any advice on how we can get the message to your colleagues on this issue?

A: Your industry needs to advocate for these changes through the voices of your consumers–the very people who depend on the lifesaving therapies are the best advocates. They have the best stories because they demonstrate in real life terms the need for these funds and for increased access to care. The consumer representatives that I hosted here for the QSEAL presentation spoke quite eloquently on this issue. I invite you to come in and meet with Congressional staffers. The staffers keep us informed.

Right: Congresswoman Solis reviews a document with her media director, Edith Robles.

Q: You were kind enough to participate in the presentation of the QSEAL certification awards recently, why did you feel that was important?

A: There are so many of your members doing innovative research, and that should be recognized by members of Congress for the impact your work has on the lives of so many people in our districts. It is wonderful that we have such leadership from PPTA in an area that impacts people worldwide. People are looking at better lives through many of these drugs, therapies and medical services and the demand will increase as our aged population continues to grow. People need better access to these therapies to combat disease and improve their quality of life. I've always been an advocate for that and I believe QSEAL contributes to that. As long as the industry does its job with due diligence, our part will be to obtain the support you need to continue offering quality service.

Q: You are familiar with the work of one of our members in particular–Alpha Therapeutic Corporation–that has a facility in your district right?

A: Yes. In fact, I've even toured the facility there. Alpha employs a large pool of employees from my district. Alpha's work also has an impact on the smaller vendors in the area. They are important corporate citizens that help to sustain our local economy.

Q: How can PPTA more effectively tell our story to members of Congress?

A: As I've said, consumers that depend on your therapies are your most vital messengers. Physicians who voice the importance of your products and the impact these products have on the lives of so many people are key – particularly doctors in hard-pressed areas like our district. It would be good to continue your outreach efforts in Congress and provide Members with brief messages on specific issues. But more importantly, the industry should educate and work with Congressional staff in order to be more effective.

Congresswoman Solis greets PPTA President, Jan Bult

Your industry needs to advocate for these changes through the voices of your consumers—the very people who depend on the lifesaving therapies are the best advocates. They have the best stories because they demonstrate in real life terms the need for these funds ...

Q: What health issues do you think will dominate the agenda of the second session of the 107th Congress?

A: I believe we'll see the prescription drug benefit for Medicare come back as an issue. When the anthrax scare hit, where do you think people in our district went to get drugs–to Tijuana, Mexico. Why? Because the prices for antibiotics are a quarter of what they are in this country. We need incentives for pharmaceutical companies to reduce costs of their products. We need to find out and provide better access to health care for all people–from birth to death. As the baby boom ages, we will need to look into more research. We may not have the income to take care of our ailments as the population ages. I would like to see more public-private partnerships developed to address these needs – particularly for emerging populations. The Latino population is the fastest growing population in our area. By 2050, the majority of the population in the West/ Southwest will be Latino and 1 in 3 will be a minority. We must take care of this emerging group. We can do this by giving them a place at the table as programs are developed and as discussions take place. I would like to see a bigger effort to get more physicians in our communities. Access is a primary issue.

Thank you Congresswoman for your time.

Commentary

Consumer Perspective on ABRA/PPTA Merger

Miriam O'Day,
Alpha-1 Foundation,
Senior Director, Public Policy

The ABRA/ PPTA merger offers new and exciting opportunities for consumers to partner with industry. We view the merger of ABRA/PPTA as a signal that industry is coordinating efforts to improve communication and further quality standards. Health policy and general communication are areas open for industry consumer collaborations; it is our hope that the merger will build upon existing partnerships, use successful models and extend to new as yet unexplored areas.

PPTA has a history of effective partnerships with consumers and unlimited opportunities exist for collaboration with the members of ABRA. PPTA seeks consumer input through the Patient Notification System (PNS) Working Group, Reimbursement Working Group and by including consumers in business forums. The PNS Working Group is a progressive model that grew out of the consumer initiative for direct patient notification of product recalls and withdrawals. This initiative prompted the formation of a consumer coalition, followed by industry and government embracing this program; resulting in implementation with the input of all the stakeholders. Finally, quarterly meetings of the PNS Working Group solicit consumer input into the notification system and ongoing partnerships in the promotion and oversight. This cooperative model can be implemented in many areas of health policy.

Forums that incorporate consumer input into policy decision-making are crucial, particularly in chronic disease where the consumer perspective is essential to health care and health policy. Trends in the healthcare system pose serious challenges to access to care for individuals with chronic disease, including proper diagnosis, treatment, reimbursement, safety and supply. For instance, individuals affected with the genetic lung deterioration characteristic of Alpha-1 will spend an average of five years and see seven doctors prior to an accurate diagnosis leading to appropriate therapy.

Informed consumers improve health outcomes and reduce health care costs. And in the regulatory and policy area, consumers bring ethical and social perspectives to the discussions that are often overlooked.

It should not be overlooked that many consumer organizations partner with health care professionals and utilize a Medical and Scientific Advisory Committee (MASAC). The Alpha-1 Foundation MASAC is a decision-making body that determines the research agenda, provides peer grant review and functions in an advisory capacity on scientific or medical health policy issues. The Alpha-1 Foundation MASAC is comprised of members with clinical and scientific experience, includes a bioethicist, and brings an extra layer of expertise to lay advocacy and advisory roles. For example, with the help of MASAC, the Alpha-1 Foundation formed a Liaison Working Group to expedite the development of new therapeutics for the treatment of Alpha-1. This group includes members of industry, government (FDA and NIH), consumers, scientists and clinicians.

It is our hope that the newly-merged organization will seize this opportunity to utilize the expertise of those advocating on behalf of frequent plasma recipients. Consumer input will assist ABRA/PPTA in developing a proactive industry that is "in touch" with consumer needs and concerns. Congratulations on your merger. We look forward to working cooperatively with you into the future. ●

Harvard Study on BSE Risk in US

On the last day of November, the US Department of Agriculture released a landmark study by Harvard University that shows that the risk of Bovine Spongiform Encephalopathy (BSE) occurring in the United States is extremely low. The report showed that early protection systems put into place by the USDA and the Department of Health and Human Services have been largely responsible for keeping BSE out of the US and would prevent it from spreading if it ever did enter the country. Even so, officials outlined a series of actions to be taken that would continue strengthening programs to reduce that risk even further. The risk assessment was commissioned by USDA and conducted by the Harvard Center for Risk Analysis. It evaluates the methods by which BSE could spread if it were to enter the United States.

"Based on three years of thorough study, we are firmly confident that BSE will not become an animal or public health problem in America, " said Dr. George Gray, deputy director of the Harvard Center for Risk Analysis and director of the project.

The USDA will take a series of actions to strengthen its BSE prevention programs as a result of the recommendations within the Harvard study. First, USDA will have the risk assessment peer reviewed by a team of outside experts to assure its scientific integrity. Second, the USDA will more than double the BSE tests it will conduct this fiscal year. Third, the USDA will publish a policy options paper outlining additional regulatory actions that may be taken to reduce the potential risk of exposure and ensure that potential infectious materials remain out of the US food supply. Options being considered include: prohibiting the use of brain and spinal cord from specified categories of animals in human food; prohibiting the use of central nervous system tissue in boneless beef products; prohibiting the use of vertebral column from certain categories of cattle – including downed animals. In addition, the USDA will issue a proposed rule to prohibit the use of certain stunning devices used to immobilize cattle during slaughter. Last, USDA will publish an Advance Notice of Proposed Rulemaking to consider additional regulatory options for the disposal of dead stock on farms and ranches.

BSE has never been detected in US cattle, nor has there been a case of the human form of the disease, variant Creutzfeldt-Jakob Disease (vCJD) detected in the United States.

A complete copy of the Harvard Report can be obtained from the USDA official website at www.usda.gov. ●

INFORMATION ABOUT GOVERNMENTAL ACTIONS WITH REGARD TO HUMAN TSEs

Updated 18 December 2001

ISSUE	EUROPEAN UNION																														
	Austria	Belgium	Denmark	Finland	France	Germany	Greece	Ireland	Italy	Luxembourg	Netherlands	Portugal	Spain	Sweden	UK	Switzerland	Norway	Iceland	Bulgaria	Czech Republic	Poland	Slovakia	Slovenia	Romania	Canada	US	Australia	New Zealand	Hong Kong	Japan
1 Total number of BSE cases (number incl. imported animals)	1	47	5	1	344	119	1	647	33	1	36	605	67	0	181,255	391	0	0	0	2	0	5	0	0	3#	0	0	0		3
2 Number of variant CJD cases	0	0	0	0	5	0	0	1	0	0	0	0	0	0	101	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
3 Use of local plasma in manufacture of medicinal product	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●
4 Local blood collection for labile products	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●
5 Exclusion of donor accumulation x months in the UK between 1980 and 1996	6	●	●	6	12	6	6	●	6	●	6*	●	●	●	●	6	●	●	6	6	6	6	●	●	3	3*	6	6		6
6 Exclusion of donor accumulation x months in Ireland between 1980 and 1996	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	6	6	6	●	●	●	●	6	●		●
7 Exclusion of donor accumulation x months in France from 1980 to the present	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	6	6	●	●	●	3	60*	●	●		●
8 Exclusion of donor accumulation x months in Portugal between 1980 and 1996	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●
9 Exclusion of whole blood but not source plasma donors accumulation x months or more in Europe from 1980 to the present	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	60*	●	●		●
10 Exclusion of military personnel, civilian military employees and their dependents who resided at US military bases in Northern Europe (Germany, UK, Belgium and the Netherlands for 6 mos. or more from 1980 through 1990, or elsewhere in Europe from 1980 through 1996	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	○*	●	●		●
11 Exclusion of donors who have lived in European countries where mad cow disease has been reported.	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	60	●	●		●
12 Exclusion of donors who have injected bovine insulin since 1980 unless confirmation that product was not manufactured in the UK between 1980 to the present	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	○*	●	●		●
13 Exclusion of donors who have received blood transfusions in the UK from 1980 to the present	●	●	●	●	●	○	○*	○*	●	●	○*	●	●	●	○**	●	●	●	●	●	●	●	●	●	●	○*	●	●		●
14 Recall of batches with suspected or confirmed classical CJD	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●
15 Recall of batches with suspected or confirmed variant CJD	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●
16 Leucoreduction required for labile products	●	●	●	●	●	●	●	●	●	●	○	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●
17 Leucoreduction required for plasmapheresis	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●
18 Leucoreduction of plasma for fractionation	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●		●

KEY:

- ● Yes
- ● No
- ○ Recommended by Health Authorities/health advisory body
- * Proposed but not yet confirmed
- ** Only introduced by the national blood and plasma collection organisation
- # Only in imported animals

OFFICIAL REFERENCES:

1. Australian Department of Health and Aged Care, www.health.gov.au/
2. Australian Rad Cross, www.arcbs.redcross.org.au
3. Canada Blood Link BC, www.bloodlink.bc.ca
4. Council of Europe SP-HM Committee *Inquiry on the possible prevention of vCJD*
5. Irish Blood Transfusion Service http://ibts. healthyirish.com
6. Office International Des Epizooties, www.oie.int
7. The UK Creutzfeldt-Jakob Disease Surveillance Unit, www.cjd.ed.ac.uk
8. United Kingdom Department of Health
9. US Department of Health and Human Services, Food And Drug Administration, Guidance for Industry, August 2001

This document has been prepared by the Plasma Protein Therapeutic Association (PPTA) Europe and provides a review of governmental actions with regard to human TSEs. The document is, to the best of the Association's knowledge, based upon data, information, articles, and scientific literature that are currently available. If you have additional information on this issue please inform the Association: PPTA Europe, Boulevard Brand Whitlock 114/5, 1200 Brussels, Belgium, tel: +32(0)2.705.58.11, fax: +32(0)2.705.58.20, e-mail: ppta@pptaglobal.be.

BSE & CJD Updates




The recent WHO weekly Epidemiological Record included an update on the hazard of transmission of variant Creutzfeldt-Jakob Disease (vCJD) by blood and blood products. In that report, it states: "To date, no epidemiological evidence suggests that vCJD has ever been transmitted by blood transfusion or the use of plasma derivatives." It also states that a balance is needed between known risks and product supply requirements against any possible risk of transmission. ●

Japan has taken action to restrict blood donations from people who have stayed six months or more in Belgium, the Netherlands or Italy to prevent possible human infections of mad cow disease, according to health ministry officials there. The Health, Labor and Welfare Ministry has notified the Japanese Red Cross Society about the blood donation restrictions. A health ministry panel had previously barred blood donations from those who have stayed a half-year or more in Britain, France, Germany, Ireland, Portugal, Spain and Switzerland. Japan confirmed its third case of mad cow disease on December 2. ●

Austrian leaders are reassuring consumers that eating beef is safe following the first case of mad cow disease found there. Austrian agriculture seems in a good position to withstand a large-scale bovine spongiform encephalopathy (BSE) crisis as most of its businesses are small, family-run farms with an average of barely 20 cows. The cause of the disease remained uncertain. ●

The discovery of the first-ever case of BSE in Finland could affect the Finnish meat exports according to the minister of foreign trade there. The Baltic Countries banned the import of meat and live animals from Finland on the same day that the discovery of BSE case was announced there (December 7). ●

Slovakia has reported more cases of mad cow disease than any other central or eastern European Country–four out of 22,700 animals tested–with the latest one being confirmed in late November. Nevertheless, the State Veterinary Administration Director Dusan Hlinka reported that the situation should be seen in a wider context. "Hungary started comprehensive monitoring of cattle only in the middle of November, and we don't know when Poland will start monitoring. Romania and Bulgaria are just preparing for it." In his view, monitoring in these countries will also identify cases of Bovine Spongiform Encephalopathy (BSE). The Czech Republic this year reported two cases of BSE out of 95,000 tested animals, and Slovenia reported its first. In

(Continued on page 17)

Profile:

With Honors … James F. Crispen, MD

A pioneer in the plasma industry, Dr. James F. Crispen, has devoted over 30 years to the safe collection of plasma and to the training and development of physicians and physician substitutes within the plasma collection facility. Always a strong advocate and supporter of the Association's programs and activities, Dr. Crispen recently retired from Sera-Tec Biologicals after serving as its Medical Director since 1969.

A founding father of ABRA, Dr. Crispen was elected its first President in 1972 and served on the ABRA Board of Directors until 1985. "The early days of ABRA were not pleasant," he recalls. "It was difficult work." Dr. Crispen advocated industry practices to groups worldwide and was actively involved in the development of collection standards for developing countries through the World Health Organization. Being the only representative from the US collection industry among a panel of European national nonprofit representatives, he recalls speaking for the US standards for collection volumes (still in place today).

Doctor Crispen was also an aggressive champion of donor compensation, arguing that it would be "unethical" not to remunerate donors, who spend hours donating and being the subject of a battery of screening tests and examinations. "In the US, donors are a critical part of the for-profit industry; there is no reason for them not to be rewarded for their contributions," he argued before regulatory authorities. He reasoned that the plasma collection industry is a legitimate, ethical pharmaceutical and medical endeavor. "From the donor to the collection facility, from the fractionator to the hospital to the patient–everyone benefits from the work of the plasma industry," Dr. Crispen declares.

In the early days, Dr. Crispen encouraged the Association to become more involved in the scientific arena and to educate physicians and consumers about plasma therapeutics. Since those early days, he continued to share his expertise with ABRA leadership and committees to develop messages and programs that have raised the bar for the plasma collection industry. Most recently on behalf of ABRA, Dr. Crispen played a significant role in the development of the Workshop for Physician Substitutes in 1999 and the video training component, Training Physician Substitutes in Examination Techniques.

"In the US, donors are a critical part of the for-profit industry; there is no reason for them not to be rewarded for their contributions,"

Dr. Crispen graduated from Franklin & Marshall College, Temple Medical School, and did his fellowship in Hematology at the University of Michigan. For 35 years, he practiced hematology/oncology and was the Director of the Blood Bank at a large medical center in Harrisburg, Pennsylvania.

He was significantly involved in the research for establishing safe and effective dosages for the first Rho(D) immune globulin therapeutic used to prevent hemolytic disease of the newborn due to Rh incompatibility. This development was a significant milestone for industry. "Jim contributed very significantly to our understanding of the proper dose of Rh Immune Gloublin," says Dr. David Ciavarella, Medical Director at Ortho-Clinical Diagnostics and chairman of the ABRA Medical Directors Committee. "Along with Bill Pollack and others, he designed and executed the studies that established that a dose of 20 micrograms anti-D/per mL RhD+ Red cells was required to suppress immunization. This work was adopted throughout the world."

Well-respected as a clinical hematologist, Dr. Crispen carried on his research on Rh immune globulin in conjunction with heavy patient care responsibilities. "Having started practice in 1963," he says, "I was in a unique clinical position to see first-hand and to appreciate the tremendous good that plasma products do for patients. Prior to their availability, there simply was no prevention or treatment for many fatal conditions."

Joseph Rosen, President of Sera-Tec Biologicals Ltd. and ABRA's Chairman of the Board, applauds Dr. Cripsen's contributions, "As Medical Director for Sera-Tec for the past 32 years, Dr. Crispen contributed heavily to the success of the company. He helped establish the criteria and protocol for red cell immunization, obtained regulatory approval for plasmapheresing hemophiliacs for Factor Deficient Plasma and plasmapheresing donors who were viral marker positive, as well as other regulatory approvals to allow us to collect over 50 different plasma products."

"Every day he put his name and reputation on the line…" says Mr. Rosen. "In the early years of our industry, he was the first physician to stand up and speak for our industry. And for that, industry members should be forever grateful for his contributions."

Dr. Crispen's positions as Chairman of Central Pennsylvania Blood Bank, Board member of Pinnacle Healthcare, and Chairman of Inclinator Company of America (manufacturer of home elevators and wheelchair lifts) will keep him busy in his retirement. A pilot for 35 years, Dr. Crispen plans to enjoy his free time by flying his pressurized Barron and motor glider, playing golf and spending more time with his wife Susan, their four children and four grandchildren. ●

BSE & CJD Updates …

(From page 15)

Western Europe, the lowest instance of BSE in countries is Denmark with eight cases. ●

A woman who participated in pioneering drug trials for variant CJD has died. Professor Stanley Prusiner had invited the young woman to participate in the study earlier this year. Within three weeks of her treatment, she had shown improvement and was able to walk unaided. The woman continued taking the drug when she returned to the UK but was taken off the drug after complications set in. ●

California-based Bio-Rad Laboratories, Inc. makes kits that identify mad cow disease in slaughtered cattle. BioRad is scheduled to supply test kits to the Japanese who have initiated nationwide testing of all cattle. Japan annually slaughters 1.3 million cows for beef. The company already provides 65 percent of the tests used in Europe and has sold 3.2 million tests since early in 2001. ●

A website established by the US Food and Drug Administration to disseminate information on transmissible spongiform encephalopathies (TSEs) including the agency's action plan titled "Transmissible Spongiform Encephalopathies including Bovine Spongiform Encephalopathy and Chronic Wasting Disease" has several key areas worth noting. The first is to prevent exposure of Americans to agents of TSEs through human and animal food products; to prevent exposure of Americans to agents of TSEs through blood transfusions or tissue transplantation; and to establish a risk of TSEs and their protential transmission through FDA-regulated products. The website can be found at www.fda.gov/oc/opacom/hottopics/bse.html. ●

PPTA Hosts Consumer Meeting

By Julie Birkofer, PPTA North America

Dr, Steve Nightingale of the Department of Health and Human Services addresses the PPTA consumer meeeting held recently.

The Plasma Protein Therapeutics Association (PPTA) sponsored a meeting for representatives of various consumer organizations in Washington DC in mid December. The meeting addressed concerns on several topics–primarily Medicare reimbursement issues, industry data collection and distribution and the Patient Notification System. There was an excellent turnout. The following patient groups participated: Immune Deficiency Foundation; National Hemophilia Foundation; The Factor Foundation of America; Hemophilia Federation of America; Alpha-1 Foundation; Alpha One Association and the Committee of Ten Thousand. The American Red Cross also sent representatives. PPTA member companies were all represented and we were joined by staff from Wyeth-Ayerst Pharmaceuticals.

Medicare Reimbursement

The focus of the morning session of the December 12th meeting was an update and strategy discussion of the Hospital Outpatient Prospective Payment System (HOPPS). PPTA hosted the meeting that combined industry members of the Federal Government Affairs and Reimbursement Committees along with representatives from consumer and patient group organizations. PPTA scheduled this meeting immediately prior to the FDA Blood Product Advisory Committee meeting to facilitate travel schedules and optimize attendance.

PPTA presented an overview of the HOPPS and background information on the pass-through reductions contained in the November 2, 2001 final rule. Industry and consumers agreed that the focus should be on 2003 when most products will be moved out of the pass-through into permanent APCs. One key topic discussed was the importance of distinguishing plasma-derived and recombinant analog therapies from blood and blood products. Apparently there exists some confusion among CMS and HHS staff regarding the different classification of labile and stabile products. PPTA intends to clarify with CMS and HHS staff the differences between the two products and to educate both organizations on: What the products are of PPTA members, how they are currently reimbursed and why that level of reimbursement is inadequate.

The Chairperson of PPTA's Reimbursement Committee, Mary Ann Tomasso, gave a presentation that provided "real world" examples of what the impact of HOPPS reductions would have on providers. Ms. Tomasso's examples clearly illustrated that the HOPPS final rule would result in severely restricting patient access to plasma-derived and recombinant analog therapies.

A presentation by PPTA staff designed to energize the group to work together with Congress and the Administration on patient access issues followed. PPTA staff stressed the need to work together in 2002 to lay the foundation for 2003 and that it will be a competitive field jockeying for adequate reimbursement rates. PPTA will continue to work with consumer groups to identify key messages for CMS and the Hill.

The consumer groups suggested that they could partner with providers and provide doctors, hospitals, emergency departments and home care companies with educational materials on the changes in hospital outpatient billing and coding. Those groups that were represented at the meeting demonstrated a willingness to engage on this issue and an understanding that doing nothing is not a viable option.

PPTA staff and the Chairperson of the Reimbursement Committee engaged the group in a lively discussion of future strategies that will impact the proposed rule coming out in 2002 to implement the transition from pass-through payments to permanent APCs. Staff solicited input from the participants and developed the following strategy:

- Begin a meaningful dialogue with CMS – Jan./Feb. 2002
- Partner with consumer /patient groups to conduct joint meetings with CMS and Congress – Jan./Feb. 2002
- Formulate a "White Paper" proposal that clearly articulates PPTA's position on HOPPS and states preferred mechanism for payment– March/April 2002
- Bring "White Paper" proposal to CMS, with "buy-in" and support from consumer/ patient communities–April/ May 2002
- Support proposal to CMS until proposed rule
- Comment on proposed rule.

PPTA staff will continue to work with consumer organizations to educate and advocate to assure patient access. The consumer groups also expressed gratitude to PPTA for hosting the meeting and expressed an ongoing desire to continue to "partner with industry."

Industry Data Collection

Recognizing the need for better data regarding supply and use of plasma protein therapeutics, members of the group discussed possible opportunities for increased reporting.

Dr. Stephen Nightingale, Health and Human Services, updated the group on plans to initiate a data collection network that would provide current usage information from patients. HHS has obtained $600,000 for funding such an effort. Dr. Nightingale began his presentation by stating "I applaud your work here today. The PPTA System of data reporting that monitors supply has worked better than it was ever perceived. PPTA has made a huge contribution by getting the system established. It looks simple but it isn't." Exactly what data will be collected in addition to those already collected by PPTA remains an open issue. However, it is clear that all stakeholders share a desire to have the most timely and meaningful data available.

Patient Notification System

Attendees were brought up to date on the migration of the Patient Notification System (PNS) to a new web-based system for easier consumer access. The level of consumers registered on the system is up 1,500 from one year ago and this marks a series of key marketing efforts on the parts of consumer and industry groups. The new website for PNS is www.patientnotificationsystem.org.

Several months ago the PNS working group prepared a consumer survey to try to find out about patient knowledge of the system. The final summary report was given regarding the survey. Almost 900 surveys were returned and the marjority of the responses indicated that a lack of knowledge of the system was the biggest barrier to consumer registration. Almost half of those returning the forms were already registered with the PNS. The attendees agreed that there was a need for continued marketing of the PNS to consumers and that a strategy for developing additional techniques will continue.

PPTA suggested that regular articles in consumer magazines and newsletters would be an effective means of reaching consumers and those represented at the meeting agreed. PPTA plans to provide regular information articles to consumer groups to reach those who are not yet registered with the PNS. ●

WHO Global Collaboration for Blood Safety Working Group

By Johan Prevot, PPTA Europe

The World Health Organisation (WHO) AIDS Summit that was held late in 1994 recognised, among other things, the need for a global initiative to put blood safety as an international priority. As a result, the 48th World Health Assembly formally established the Global Collaboration on Blood Safety (GCBS) in May 1995. Its mission was set to improve collaboration, utilize existing expertise, develop realistic and effective actions and promote dialogue among organizations and institutions involved in the area of blood safety, in order to improve the safety of the global blood supply. Particular attention was given to developing countries, where still today and despite progress over the past decade, too many people die either because of a lack of blood and blood products or because they are treated with untested blood transfusions. Poor Quality Management and a lack of finance in most of these countries are at the root of the bad quality of care provided to patients. Therefore, the GCBS prioritised its objectives to focus principally on these issues: encouraging governments to recognise the importance of blood safety and to establish national blood programmes and help governments, upon request, to identify national blood safety priorities and implement all measures that will maximise the safety of blood and blood products from donor to patient.

To ensure its efficiency, expertise and integrity, the GCBS working group serves as a platform, made up of a wide range of representatives and specialists from various institutions involved in blood product safety from developing and developed regions and countries and internationally renowned organisations (the Plasma Protein Therapeutics Association being one of them). During their first meeting in November 2000 in Geneva, the GCBS established three subgroups (see chart).

The main objectives of the plasma derivatives programme of the GCBS Working Group on Plasma Issues are:

- The creation of a Guide
- Information/Education Workshops
- Technology Transfer

The Guide will be designed to help developing countries' governments in their decision-making with respect to the safety and availability of plasma derivatives. Too often in the past, the safety of blood and related derivatives has been compromised in such countries, because important decisions were misunderstood or simply wrong. Among the components of the Guide an Aide-mémoire will be elaborated to lay down key elements, which need to be taken into consideration by authorities. Fact sheets, in which guidelines are developed to advise developing countries on the tools and means available to further enhance the safety and quality of plasma derivatives, will also be available. For example, a fact sheet on Plasma Contract Fractionation Programme has already been drafted.

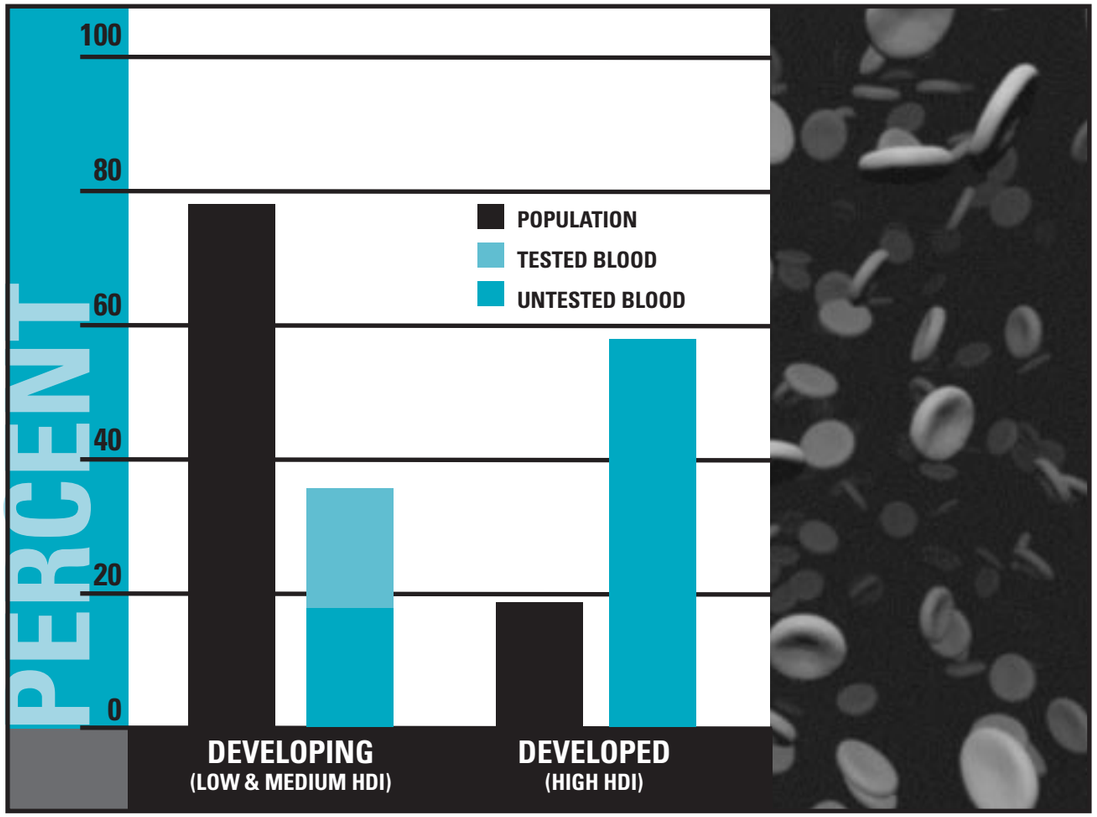
In order to meet the needs of the local population, developing countries are offered alternative solutions besides importing finished product or building fractionation centres. The Plasma Fractionation Programme enables developing countries to use 'custom fractionation' –that is to say to send local plasma to established fractionators abroad and to have end-products returned to them. Custom Fractionation, sometimes known as contract or toll fractionation may be used in developed countries as well when the economies of national-based fractionation is illogical or simply that the quantity of plasma available is too small. These fact sheets will eventually comprise modules, which will be brought together in one package as the Guide to the safety and supply of plasma-derived medicinal products. In the meantime, the modules can be used separately.

The second component of GCBS's Plasma Issues Group is workshops to inform important stakeholders, regulators, policymakers, licensing authorities and inspection organisations about state-of-the-art technologies and to identify national priorities. These workshops answer questions by bringing leading independent experts to the meetings. The first 'pilot' workshop took place in Cuba in late October 2001 (WHO Regional Workshop on Quality Assurance & Safety of Plasma Derivatives). As a result, advise was provided to representatives of 11 Central and South American countries.

The GCBS aims to improve the process of guaranteeing a safe and adequate supply of blood and blood derivatives by building on collaboration, knowledge and conventional wisdom. Its various initiatives such as the Plasma Derivatives Programme are seen by many as being crucially important steps toward the improvement of blood safety throughout the world. ●

GCBS's 3 Groups

1. Policy Process	Objective: Facilitate international communication relating to Blood Transfusion Service (BTS) policymaking.
2. Quality Assessment and Assistance	Objective: Develop Standards and identify models
3. Plasma Issues	Objective: Implement a plasma derivatives programme



Second Workshop on Partnering for Rare Disease Therapy Development

By Edward Hutt, PPTA Europe

‘There are a number of potential advantages in the European Union to have a medicinal product designated as an ‘orphan medicinal product’.

It was to investigate such opportunities that the Association was represented at a workshop in Paris on this subject, organised by EPPOSI, the European Platform for Patients’ Organisations, Science and Industry, in October 2001.

The chief advantage conferred on orphan medicinal products is market exclusivity for ten years. In order to encourage further development of treatments for conditions which affect fewer than five per 10,000 persons, marketing approval is facilitated in the following ways. A special committee (Committee for Orphan Medicinal Products, COMP) provides assistance on developing clinical trial protocols, and works with the CPMP (Committee for Proprietary Medicinal Products) to speed up approval; European Union sources of development funding can be obtained more easily; and marketing authorisation fees are reduced. In addition, Member States are encouraged to put in place additional incentives in areas such as taxation, pricing and reimbursement.

LEFT: Yann Le Cam, European Organisation for Rare Disorders (EURORDIS). RIGHT: Gérard Delfau, Senator, French Parliament.

The workshop provided a good opportunity for patients, researchers, manufacturers, legislators and regulators to review progress so far and to explore ways in which this progress can be accelerated. Senator Gérard Delfau hosted the first day at the French Senate, and the sessions on the second day took place at the Hôpital Broussais in Paris where the Orphanet rare disease web resource and EURORDIS, the European Organisation for Rare Diseases, are based. Speakers participated from the European Commission (Directorate General DG Enterprise and DG Research); the European Medicines Evaluation Agency (EMEA), including COMP staff and national representatives; national administrations (Ministry of Research, France); patient groups (EURORDIS; European Parkinson’s Diseases Association;

(l to r) André Lhoir and François Meyer, Belgian and French representatives on the Committee on Orphan Medicinal Products (COMP)

Palais de Luxembourg, seat of the French Senate

Fighting Blindness, Ireland); researchers (Dr Gérard Lenoir, Hôpital Necker, Paris and Dr Frédéric Becq, of Poitiers University) and companies (including Serono, Catalyst BioMedica, BioGestion, Genzyme).

The attendees were reminded that the US had implemented similar measures in 1983 and Japan had done so ten years later. Australia, New Zealand and Singapore also put in place legislation before the European Union passed its orphan medicinal product regulation in 1999. While the speakers were pleased that measures are now in existence in Europe there was concern that there were no more approvals of orphan medicinal products in Europe, and that Member States were not doing more on a national level to encourage their development and commercialisation.

Bruno Hansen from DG Research identified the opportunities for EU funding in the Framework Programme VI, in which genomics and biotechnology for health will be a priority. This framework will run from 2002 to 2006 and has 17% more funds available than had Framework Programme V.

It is clear that many of the diseases treated by products made by Association members are classified as rare diseases. They are also of a life threatening or chronically debilitating nature. However, it is also necessary for the sponsor to demonstrate that no satisfactory method of treatment of the condition in question exists or, if such treatment does exist, that the new treatment will be of significant benefit to those affected by the condition. None the less it is possible to apply for designation of orphan status for a new therapeutic indication for an already authorised medicinal product. In this case a separate marketing authorisation will cover only the orphan indication(s). However, it is not clear whether in practice any business benefit could be obtained by such a designation as a higher price may only encourage 'off label' use of the identical but cheaper drug marketed for other indications.

In conclusion, member companies are encouraged to consider orphan medicinal product designation when evaluating the business case for developing a new drug. ●

See also:

- **http://www.emea.eu.int/htms/human/press/comp.htm**
- **http://orphanet.imfobiogen.fr/**
- **http://www.eurodis.org**
- **Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products**
- **Commission Regulation (EC) No 847/2000 of 27 April 2000 laying down the provisions for implementation of the criteria for designation of a medicinal product as an orphan medicinal product and definitions of the concepts 'similar medicinal product' and ' clinical superiority'**

PPTA Profiles:

Julie Birkofer joins the PPTA Staff as Director, Health Policy. Prior to joining PPTA, Ms. Birkofer served in the office of former Pennsylvania Governor Tom Ridge as the Associate Director of Domestic and Health Policy. During her tenure in the Governor's office, Ms. Birkofer worked closely with the Pennsylvania Departments of Aging, Insurance and Health to ensure that the Commonwealth's agenda was advanced on Capitol Hill.

On behalf of Highmark, Inc., Ms. Birkofer was the Senior Government Affairs Representative and focused on major health insurance issues such as the Patients' Bill of Rights and Medicare prescription drug coverage. In addition, she served as a Vice President at R. Duffy Wall & Associates, Inc., a government relations consulting firm. Bell Atlantic Corporation, the Betty Ford Center, the Hazelden Foundation, the Home Care Association of New York, Torchmark Corporation, the American Ambulance Association, Texas Health Resources and the Garden State Cancer Center were among the clients represented by Ms. Birkofer over a four-year period.

She also served as the Senior Congressional Representative for the 20,000 member American Chiropractic Association (ACA) for five years. Ms. Birkofer played an integral role during the health care reform debate in the 103rd Congress. In 1995, the department's team efforts were recognized by receipt of the prestigious "Excellence in Government Relations" award from the American Society of Association Executives (ASAE) for best overall federal legislative program. Before her tenure at the ACA, she worked as a policy analyst at the American Medical Peer Review Association, now known as the American Health Care Quality Association.

As PPTA's Director of Health Policy, Ms. Birkofer will work closely with the the PPTA Federal Government Affairs and Reimbursement Committees. Her focus will be to pursue legislative strategies and solutions that will enhance and protect patient access to the life-sustaining therapies produced by PPTA member companies. Ms. Birkofer looks forward to fostering stronger relationships with the consumer and patient communities and identifying synergies to achieve success. ●

Craig B. Mendelsohn MD, JD

Craig B. Mendelsohn MD, JD, joins PPTA as Director of Regulatory Affairs. Prior to joining PPTA in November 2001, Dr. Mendelsohn was the Assistant General Counsel for FDA Affairs at the American Red Cross. At ARC, he worked with the quality, regulatory and government affairs departments providing regulatory and general legal guidance primarily in matters related to FDA oversight. He also provided guidance on blood and plasma related issues concerning the Department of Transportation and Occupational Safety and Health Administration. Prior to his tenure with the Red Cross, Craig practiced law at the offices of Hogan & Hartson as an Associate in the Food, Drug, Agriculture and Medical Devices group, and at the offices of Hyman, Phelps & McNamara in the areas of food, drug and medical device law. Craig also held a private Opthalmologic practice for 10 years before entering his career in Law.

Craig received his Bachelor of Arts in Chemistry in 1976 from Emory University and his Juris Doctor from the Georgetown University Law Center in 1994. In 2000, he receive the ARC Tiffany Award, for superior employee excellence in the area of professional/technical services. He has co-authored articles on medical device law and policy.

As Director of Regulatory Affairs for PPTA North America, Dr. Mendelsohn will evaluate and report on industry issues of a regulatory nature, and support related Association liaison activities with regulatory agencies and consumer groups. He will work closely with various Association committees to develop consensus positions and industry guidelines, as appropriate. ●

Looking Forward ...

(From page 6)

matically from that original challenge to being the most desired source of plasma for further manufacture into life-sustaining plasma therapeutics.

Many of the changes took root in the voluntary industry initiatives developed by ABRA–beginning with the QPP program, established in 1991. Through the QPP Program, viral marker rates have been reduced, comprehensive employee training programs have been instituted, a national donor deferral registry was established, and the "qualified donor" standard was initiated (where only repeat donors are acceptable for plasma for fractionation). This program has been enhanced over the years and subsequently expanded outside the United States to facilities in Europe. The development of a companion QPP program for recovered plasma was recently approved by our industry.

While ABRA represented plasma collectors and fractionators, its main activities concentrated on collection activities. Over the years, the Association conducted compliance workshops, organized a Regulatory Affairs Committee for liaison with the Food and Drug Administration (FDA) and other regulatory bodies, established committees to address standards, industry education, medical issues, and quality assurance and to represent its membership in response to the constant changes in the industry.

The major fractionators had additional issues to address other than collection activities and subsequently formed the International Plasma Products Industry Association (IPPIA), which later became the Plasma Protein Therapeutics Association (PPTA). Over the last decade, as PPTA grew, it has become clear that the industry has changed and the associations had to reflect those changes. In addition, there are recognized benefits for an industry that speaks with one voice. The accomplishments of ABRA were well recognized by PPTA, and its role in representing collector issues were acknowledged as critical to the success of the industry. Thus, the proposal to merge ABRA with PPTA was a natural outcome.

The most important concepts of the merger were to retain the total diverse membership of ABRA including not only plasma collectors and fractionators, but also diagnostic manufacturers and its Associate Members of suppliers to the industry and not-for-profit industry members; to retain a new Board of Directors with an equal number of PPTA global members and independent collector members; and to have a liaison relationship with PPTA via non-voting representation on the global board. This merger was unanimously approved by the ABRA membership at its October 2001 Annual Meeting.

With both ABRA and PPTA now under the PPTA umbrella, we can look ahead to the development of expanded services and activities and at the same time, concentrate on our individual areas of expertise. More important, we can continue to express our united industry voice. ●

On January 1, 2002, Dr. Ruedi Waeger, the President and CEO of Aventis Behring, assumed the role of Chairman of the PPTA Board of Directors. *The Source* will feature an interview with Dr. Waeger in an upcoming issue.

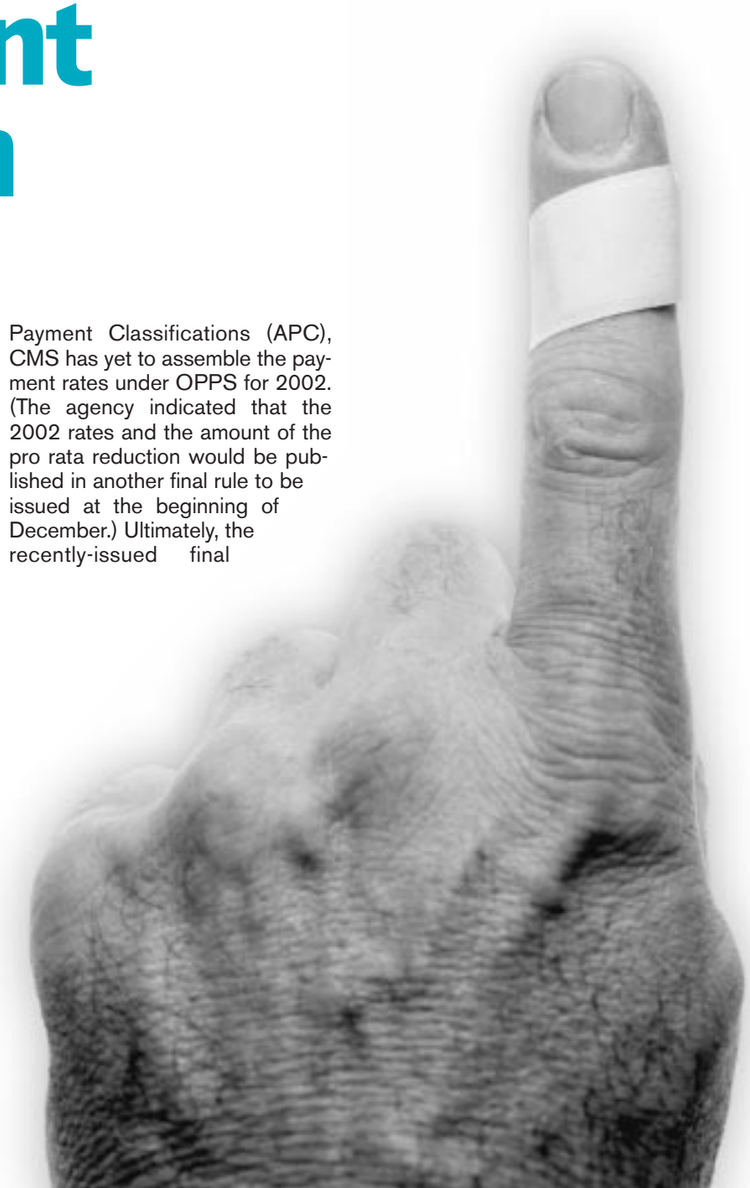
On January 1, it was my pleasure to assume the Chairmanship of PPTA. In taking on this new role, I would like to thank the former Chairman of PPTA, Thomas Glanzmann, and the former Chairman of ABRA, Joe Rosen, for their leadership in our industry. I have great respect for both gentlemen and what they have been able to achieve for the association: Thomas especially for leading the association initiatives on quality and Joe for increasing the effectiveness of ABRA.

This will be an exciting year and I welcome the opportunity to work with the member companies to establish PPTA as one of the most effective trade associations in the world. This will require a strong focus on setting priorities and a commitment to following through. Our recently merged organization, combining ABRA and PPTA, improves our ability to achieve our goals efficiently. I look forward to serving our association members, key stakeholders and the people who rely on our products to improve the quality of their lives.

— Ruedi Waeger,
Chairman,
PPTA Board of Directors

Public Policy ...

Medicare Hospital Outpatient Prospective Payment System



In early November, 2001, the Centers for Medicare and Medicaid Services ("CMS") issued a final rule regarding the hospital outpatient prospective payment system ("OPPS") 66 Fed. Reg. 55857. This rule addresses some of the issues raised in CMS's August 24, 2001 proposed rule, leaving other issues to be addressed in a separate final rule to be issued at the beginning of December. The recently-issued final rule discusses only the OPPS conversion factor and the pro rata reduction of pass-through payments in 2002. According to the final rule, payments for pass-through items in 2002 will be reduced by about 65-70%. At the same time, CMS issued a policy statement that included legislative recommendations related to OPPS that the CMS Administrator stated would result in a reduction of about 40%. In light of administrative revisions made to OPPS to mitigate the impact of the pro rata reduction, which will cause reductions in payment rates for most Ambulatory Payment Classifications (APC), CMS has yet to assemble the payment rates under OPPS for 2002. (The agency indicated that the 2002 rates and the amount of the pro rata reduction would be published in another final rule to be issued at the beginning of December.) Ultimately, the recently-issued final

rule provides a strong indication that the Medicare payment rates for member products payable under OPPS will fall in 2002.

Background

The Balanced Budget Act of 1997 mandated the new OPPS to replace the existing cost-based payment system for outpatient services. However, both Congress and CMS understood that insufficient data were available to ensure that costs of new medical devices, drugs and biologicals in outpatient procedures were adequately accounted for within the new Ambulatory Payment Classifications (APCs) under the OPPS.

As a result, in 1999 Congress established a hospital policy in the Balanced Budget Refinement Act (BBRA) to pay for new medical devices, drugs and biologicals within the OPPS, by setting aside a separate account equal to 2.5 percent of total spending in 2002, known as the "pass-through pool." An additional account was also set up for hospitals, known as the "outlier pool," equal to 2 percent of total spending in 2002 and designed to protect hospitals from high-cost patients. Both accounts would be available for a maximum of three years, the goal being to fold 100 percent of the costs of new medical devices, drugs and biologics into the APCs as soon as OPPS data were available.

At the time the OPPS was implemented in August of 2000, CMS estimated that the 2.5 percent pass-through pool would be insufficient, based on available data. As a result an across-the-board reduction in pass-through payment of approximately 50 percent would have been necessary to keep expenses contained within the 2.5 percent allotted pass-through pool. The lack of appropriate data resulted in Congress asking CMS to delay any cut in pass-through payment for new medical devices, drugs and biologicals.

The Medicare program finds itself in a similar position today. Projected expenses for new medical devices, drugs and biologicals in 2002 are expected to be $2.3 billion. However, the 2.5 percent pass-through pool is only $437 million. Congress estimates that in order to keep payments within the mandated 2.5 percent pass-through pool a payment cut of approximately 80 percent would be necessary. Clearly, a cut of this magnitude could create much greater difficulty for Medicare's 39 million beneficiaries in accessing many important health care devices, drugs, and biologicals.

Congress estimates that in order to keep payments within the mandated 2.5 percent pass-through pool a payment cut of approximately 80 percent would be necessary. Clearly, a cut of this magnitude could create much greater difficulty for Medicare's 39 million beneficiaries in accessing many important health care devices, drugs, and biologicals.

Mitigating the Impact of the Reduction by Incorporating 75% of the Estimated Pass-Through Costs for Devices into the Procedure APCs Associated with These Devices

CMS acknowledges in the final rule that a "significant pro-rata reduction could affect the availability of improved medical technology for Medicare beneficiaries." To lessen the impact, CMS has taken action administratively to reduce the size of the reduction. Specifically, CMS is incorporating 75% of the estimated pass-through costs for devices, approximately $1.4 billion, into the procedure APCs associated with these devices. While this reduces the size of the pass-through pool and lessens the pro rata reduction (from 80.7% to 65-70%), it also causes payment rates for these APCs to increase due to the incorporation of these pass-through costs. At the same time, the increases in these APCs, which account for 4% of the APCs, will cause a decrease in the payment rates for the other 96% of the APCs because of an OPPS budget neutrality requirement. Thus, reimbursement for products such as albumin that are not pass-through items will decrease in 2002 as a result of CMS's administrative actions to lessen the pro rata reduction. Again, the precise reductions in the APCs or pass-through payments will not be known until the other final rule is issued in the next month or so.

Legislative Action

In a policy statement regarding the OPPS rule, the Department of Health and Human Services (HHS) notes that the Administration is "very concerned about the potential impact the new APCs may have on beneficiaries" and is "working with Congress on various budget neutral modifications to the outpatient payment law." These modifications include the following:

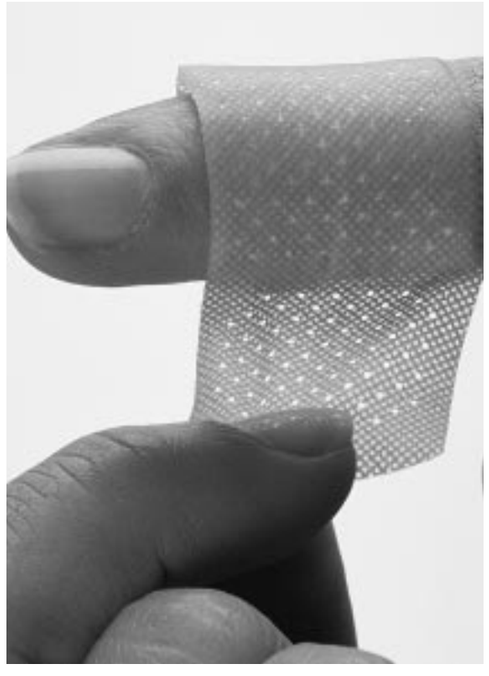
- Requiring CMS to combine the 2.5% pass-through pool and 2.0% from the outlier pool;
- Allowing CMS to use 0.5% of the combined pool to identify a limited number of sensitive preventative and diagnostic services, such as colonoscopies and mammograms, that can be held at 2001 rates should payment rates for 2002 fall below this level; and
- Requiring CMS to use the remaining 4.0% of the combined pool for payments for pass-through drugs, devices and other Congressionally identified priorities in 2002 only.

During a recent press conference, CMS Administrator Tom Scully predicted that these statutory changes would have the effect of decreasing the pro-rata pass-through reduction to approximately 40%. While the Administration is pursuing these legislative approaches, it is not guaranteed that Congress would enact these changes in a timely fashion, especially given the resistance that hospitals may provide. Perhaps for this reason, the final rule estimates a 65-70% reduction instead of discussing, as the Administrator does, a reduction in the range of 40%.

The Senate Finance Committee has already weighed in with CMS Administrator Scully expressing their "disappointment with CMS in moving forward with major Medicare policy changes without giving due weight to the views of the Senate Finance Committee." Senate Finance Chairman Max Baucus (D-MT) and Ranking Member Chuck Grassley called for implementation of the final rule to be delayed. Due to operational issues at CMS, a delay until at least April 1, 2002 is likely.

Impact of a Reduction on Pass-Through Payments

Regardless of the exact percentage of reduction that will be imposed after CMS and/or Congress complete their actions on the issue, it is important to recognize that the reduction is imposed only on a portion of the payment amount under OPPS. Currently, single source drugs and biologicals that qualify as pass-through items are paid at 95% of AWP. That payment has two components – 68% of Average Wholesale Price (AWP) is considered the "imputed acquisition costs" and 27% of AWP is considered the pass-through payment. It is only the latter figure that is subject to the percentage reduction that is ultimately imposed. Therefore, hypothetically, if pass-through payments are reduced by 50%, the pass-through component for single source products would be reduced to 13.5% of Average Wholesale Price (AWP). That component would be paid in addition to the imputed acquisition cost component (68% of AWP) for a total of 81.5% of AWP. Thus, a 50% reduction would lower payment from 95% of AWP to 81.5% of AWP. When CMS issues its next OPPS final rule within the next month or so, the percentage of the reduction and the precise payment amount for all pass-through drugs and biologicals will become apparent. ●



Regulatory Updates

In Europe

PPTA has been informed by the Dutch Ministry of Health, Welfare and Sport that they are removing the requirement to include on the product label whether donors were unpaid or compensated. This follows PPTA's advocacy for removing this labelling requirement over the last two years. The Ministry went on to note that, recognising the theoretical risk posed by vCJD, a new labelling requirement will be to include the country of origin of the plasma used.

The Dutch Haemophilia platform met on the 26 October 2001 to update its members on progress in implementing the change in treatment policy scheduled for January 2003. The platform members agreed to hold a symposium in Autumn 2002 to set out how the centralisation of haemophilia treatment in 16 centres across the country will impact the different stakeholders. PPTA will be represented on the organising committee.

The German Advisory Committee to the health Ministry, the Arbeitkreis Blut, has submitted its report on "General strategy of blood supply in the context of vCJD" to the health minister Mrs. Ulla Schmidt. The report was prepared by a number of leading scientists active in TSE research, including a member of PPTA's TSE Working Group. According to Mrs. Schmidt specific attention should be paid to the safety of blood, blood products and medicinal products in view of vCJD. According to the conclusions of the report it appears highly likely that vCJD cannot be transmitted through blood products since the abnormal prion protein is removed during the manufacturing process. All measures to reduce the risk of vCJD transmission should be taken without jeopardizing the supply of products. Mrs. Schmidt also emphasised the need to intensify the campaign to increase blood and plasma donations.

As part of the general consultation process with interested parties on the revised draft of the note for guidance on Plasma Master File (PMF) known as the "ECIII/5272/94", the European Agency for the Evaluation of Medicinal Products (EMEA) organised a workshop in London in October 2001. PPTA Europe was present in the "open session" with an imposing delegation of a dozen experts and staff. The regulators welcomed presentations on industry quality initiatives.

In the US

CJD/vCJD Draft Guidance

The Association submitted comments to the Docket on the FDA Guidance for Industry entitled, "Revised Precautionary Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products." The Plasma Collection Industry recognized that the Draft Guidance document addresses complex issues. The donor deferrals and product retrievals recommended in the Draft Guidance may potentially affect the supply of important blood and plasma therapies.

As a result of the complex format of the Draft Guidance, it is difficult to properly classify the donor and determine the appropriate actions for donor deferral, product retrieval and reporting. Industry requested the addition of a table to the document to aid the reader in determining the appropriate donor classification and to show the specific course of action that is required for each classification. Industry also requested clarification on the expectation for "appropriately counseling" donors at an increased risk for CJD and vCJD. ●

Biological Product Deviation Reports (BPDRs)

The Association is also working with FDA to implement the recommendations outlined in the FDA Guidance for Industry entitled, "Biological Product Deviation Reporting for Blood and Plasma Establishments." Centers are encouraged to use the recommended BPDR forms, specifically, the electronic version of the forms. Supporting documentation (such as donor records) should not be included with BPDRs. If additional information is needed, FDA will request it. Updates to the BPDR electronic form instructions and deviation codes have been posted on the CBER website at http://www.fda.gov/cber/biodev/biodev.htm. ●

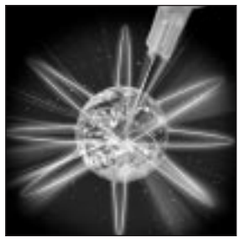
FDA Guide to Inspections of Source Plasma Establishments

The revised version (dated April 2001) of the FDA Guide to Inspections of Source Plasma Establishments has been posted on the FDA website at ma/default.htm or members may obtain a copy from the Association office, reference document number 017544. ●

Comparability Workshop

A workshop, sponsored by the Plasma Protein Therapeutics Association (PPTA) will be held this Spring in the Washington, DC, area. The purpose of the workshop is to clarify existing regulations and guidelines impacting the pharmaceutical industry. In particular, the workshop will specifically focus on "Changes to be Reported in an Approved Application" and "FDA Guidance Concerning Demonstration of Comparability of Human Biological Products." ●

Global News …



Nabi announced that it has received the approval letter from the U.S. Food and Drug Administration to manufacture Nabi-HB™, hepatitis B immune globulin (Human), in its biopharmaceutical manufacturing facility in Boca Raton, FL. According to David J. Gury, Nabi's Chairman, CEO and President, "We can now directly control the quality and supply of Nabi-HB™ from the point of vaccinating donors and collection plasma at our nine antibody collection centers, through fractionation and purification in our own manufacturing facility, and on to the marketing of the product through our sales force."

Serologicals Corporation announced that it has signed an agreement to acquire The Intergen Company, a privately-owned company that supplies a wide array of biological products and innovative technologies to the life sciences industry. Intergen's life sciences research business include Amplifluor®, a patented technology for the detection and amplification of nucleic acids, used in the discovery and development of biopharmaceutical products and nucleic acid testing. "The acquisition of Intergen represents a significant opportunity in the implementation of our strategic plan," said David A. Dodd, President and CEO of Serologicals. "Intergen's products and technologies complement our business focus and will allow us to broaden our product line to our current customers as well as afford us the opportunity to establish new customers with an expanded portfolio of products and technologies."

Pharmacia Corporation announced that it has reduced its shareholding in **Biovitrum AB** to 19 percent through the sales of shares in the new biotechnology company to two leading venture capital institutional investors: Alta Partners of San Francisco and Switzerland's HBM BioVentures (Capital V).

Thomas Lönngren, Executive Director for **The European Agency for the Evaluation of Medicinal Products,** announced the formation of a new Unit for Communications and Networking with responsibility for facilitation communications and networks between the Agency's partners. Sectors of the new Unit include: document management and publishing, project management, meeting management and conferences, information technology. The creation of this new Unit is part of the Agency's plans to develop and prepare itself for the changes in the European system for authorization and supervision of medicines expected in 2003.

ProMetic Life Sciences announced that it has closed a licensing agreement with PharmAAware SEPSIS B.V., a Netherlands-based venture company funded by ABN AMRO Capital and Theratase PLC. PharmAAware will use ProMetic's technology to develop both a diagnostic kit and a therapeutic protein for treatment of sepsis and septic shock. PharmAAware will utilize ProMetic's technology to purify Alkaline Phosphatase (AP), an enzyme known to prevent inflammation and the sepsis cascade, which has shown significant potential as an effective therapy for septic shock. PharmAAware will initially focus on exploiting the endotoxin neutralizing properties of AP to develop a therapeutic for Sepsis, and a diagnostic device to improve on the monitoring of these patients.

MedImmune announced that it has licensed worldwide rights to EphA2 technology from Purdue Research Foundation. MedImmune will be responsible for developing, manufacturing and commercializing therapeutics that target EphA2. These products will potentially be used to treat a variety of aggressive tumors, including breast, colon, prostate, lung and skin cancers, as well as to prevent metastasis.

Mitsubishi Pharma Corporation, which started operations in October, established **Mitsubishi Pharma America Inc.** and **Mitsubishi Pharma Europe Ltd.** on the same date. Located in London, the latter was created on the basis of MTP Europe, the UK subsidiary of the former Mitsubishi-Tokyo Pharmaceuticals. Mitsubishi Pharma America Inc. was established on the basis of the drug development center of Mitsubishi Chemical America Inc., whish was transferred to MPC from its parent Company Mitsubishi Chemical Corporation. Mitsubishi Pharma Europe Ltd. has integrated the London Office of the former Welfide Corporation. It will prepare for the independent marketing of argatroban, a drug for heparin-induced thrombocytopenia.

American Bio Medica Corporation announced it had entered a distribution relationship with Citadel Security Services (CSS), a supplier of state-of-the-art drug testing product and services to workplace, criminal justice, drug treatment and school programs throughout the country. The agreement includes a variety American Bio Medica's on-site drug testing products.

University of Pittsburgh researchers have identified the precursors of epidermal Langerhans cells (LCs), cells that reside in the skin and play a key role in the initiation and regulation of the immune response thoughout the body. Researchers may now be able to use these cells to manipulate and control the immune response, according to the groundbreaking study to be published in the December issue of *Nature*

Global News ...

Immunology. Through genetic engineering, the cells could be targeted for the delivery of genes encoding for specific antigens and immunoregulatory molecules, signaling either the start or stop of the immune response. The study was funded by grants from the National Institutes of Health and from the Dermatology Foundation.

Aventis Behring LLC announced that it is dedicating an incremental $1 million in annual funding to the Aventis Behring Foundation for Research and Advancement of Patient Health. The Foundation is a non-profit organization dedicated exclusively to charitable, scientific and educational purposes that advance the standard of care for persons affected by bleeding disorders.

Chronix Biomedical (Benicia, California) announced that it has filed a patent application for a serum-based test to detect BSE. The application describes a unique genetic material found in cows infected with BSE but not in healthy ones examined. A major advantage is that the animals need not be sacrificed to be tested as is the case with current methods for BSE detection. This follows an announcement in June 2001 of Chronix and the Institute of Veterinary Medicine (Goettingen, Germany) of a research collaboration.

Serologicals Corporation announced that it is a sponsor of the first annual Georgia Life Sciences Summit, recognizing and promoting the growth of Georgia's life sciences industry.

Baxter Healthcare Corporation confirmed that it will participate in the production of approximately 155 million doses of smallpox vaccine, in conjunction with Acambis Inc. US Secretary for Health and Human Services, Tommy G. Thompson, announced the contract to produce the smallpox vaccine in preparation for potential bioterrorist activities. The US government has requested that the vaccine be available within 12 months.

Cangene announced that its wholly-owned subsidiary, **Chesapeake Biological Laboratories Inc.** will participate in the production of approximately 155 million doses of smallpox vaccine in conjunction with Acambis Inc. and Baxter BioScience. CBL will provide the final filling, lyophylization and finishing stages of the manufacturing process.

Berna Biotech Ltd. announced that it has signed contracts with a number of governments for the supply of the Lacy-Vaxina Berna smallpox vaccine. Negotiations with other countries are still in progress. The current worldwide political situation has prompted a number of European governments to make enquiries at Berna Biotech Ltd. about smallpox vaccine.

Abbott Laboratories announced that it has acquired control of Vysis, Inc., a genomic disease management company that develops, commercializes and markets DNA-based clinical products providing information to the evaluation and management of cancer, prenatal disorders and other genetic diseases.

Nabi announced that it has signed a 10-year agreement with Inhibitex Inc. to manufacture its lead investigational product, an immune globulin therapy for preventing staphylococcal infections in very low birth weight infants, at Nabi's manufacturing facility in Boca Raton, Florida.

ZLB Bioplasma Inc. is forming an independent IVIG scientific pharmacist advisory board to assess immune medicine trends and provide strategic counsel. Jerry Siegel, RPh, FASHP, clinical associate professor and senior director, Ohio State University, will lead the scientific panel, to consist of pharmacy experts from leading medical universities and industry organizations.

Disease Sciences Inc. announced that it has completed its acquisition of HealthSpan Sciences Inc., a privately held San Diego-based drug development company. HealthSpan has two patent filings with a class of compounds that may have potential as a treatment for a wide range of diseases in both humans and animals. Their proposed drug analogs may be anti-microbials or immune-stimulants, which could lead to potential applications in treating chronic infections such as AIDS, Hepatitis C, or TSE diseases.

MedImmune Inc. and **Aviron** announced that they have entered into a definitive merger agreement under which MedImmune will acquire Aviron through an exchange offer and merger transaction. Aviron is a developer of live, attenuated vaccines and has vaccines for prevention of Epstein-Barr virus, parainfluenza type 3, and cytomegalovirus in clinical development.

Serologicals Corporation was recently named to the prestigious "Fast Tech 50" in the Greater Atlanta area, marking the fifth consecutive year the company has achieved this designation. "Fast Tech 50" recognizes the largest 50 high technology companies with the 21-county Metro Atlanta area, based on annual revenues.

Bayer announced that is has entered a collaboration with Axxam Srl, a newly formed Italian biotechnology company, in the field of post-genomics with the objective of developing several technology platforms for modern drug discovery. The results of genome research are thus used to develop biological test systems. Bayer has agreed to integrate its Italian research unit – at the San Raffaele Biomedical Science Park in Milan – into Axxam.

Nabi successfully completed preclinical safety studies of NICVAXtm, the company's proprietary experimental vaccine against nicotine. The vaccine is being evaluated as a novel approach for the treatment and prevention of nicotine addiction associated with tobacco use. Nabi will proceed with plans to initiate human clinical testing in the first half of 2002.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO) published a new report **"AIDS Epidemic Update 2001,"** indicating that the number of HIV infections in Eastern Europe is rising faster than anywhere else in the world. Reported figures are largely underestimated, but the latest figures reveal that there were more than 75,000 reported new infections in Russia by early November, a 15-fold increase in three years.

Haemonetics Corporation announced that it agreed to acquire Fifth Dimension Information Systems Inc. of Edmonton, Canada, a provider of information management products and services for plasma collectors and fractionators.

Baxter Healthcare Corporation announced that **BioLife Plasma Services** is the new name for Baxter's plasma sourcing organization, announced Thomas Glanzmann, president of Baxter BioScience. The new identity publicly unites all operations of Baxter's plasma services including the Community Bio-Resources and Sera-Tec Biologicals plasma collection centers and labs. BioLife Plasma Services will include a network of 101 plasma collection centers in the United States and 13 centers in Europe that supply source plasma for processing into therapeutic proteins. "With the official launch of BioLife Plasma Services, we are setting the standard for the plasma industry as it moves into the future," said Glanzmann. "Our goal is to ensure a dependable supply of life-saving products to every patient who relies on these critical therapies."

Baxter Healthcare Corporation, its team members and The Baxter International Foundation announced that they will provide nearly $2 million to organizations in New York, Washington D.C., and Pennsylvania that are addressing the mental and physical health-care needs of people affected by the tragedies of September 11. Baxter specifically sought out organizations that are providing vital services, but are not necessarily receiving large grants from other individuals and organizations funding relief efforts.

Aventis Behring announced that its facility at Floridsdorf near Vienna, Austria, reopened after a ten-month renovation. The plant manufactures plasma products for use in bleeding disorders, immunoglobulin deficiencies and intensive care medicine. The products are primarily intended for export, with countries of the European Union, especially Germany, as the main customers. More than 110 staff are employed in the production at the facility. Nearly all production equipment was renewed or thoroughly modernized and the renovation investment totaled 10 million Euro. ●

Inside the Community

News, achievements and announcements on people associated within the plasma collection and fractionation community.

Nabi announced that **Douglas Waddell** has joined the company as Senior Director, Therapeutics Manufacturing, and is responsible for all aspects of the manufacturing of its specific antibody product. Mr. Waddell joins Nabi from Bayer Corporation, where he most recently directed manufacturing operations at their Clayton, North Carolina fractionation facility.

Harold W. "Bud" Ingalls has joined Serologicals Corporation as Vice President of Finance and Chief Financial Officer. Mr. Ingalls will report to David A. Dodd, Serologicals' President and CEO, and will be a member of the company's Operating Committee. Mr. Ingalls will have full management oversight and accountability for the finance and accounting functions for Serologicals' worldwide operations. He will provide the operational and strategic expertise and leadership in key finance, accounting, business planning, control, and merger and acquisition activities. Prior to joining Serologicals, Mr. Ingalls served as president and CEO for LaRoche Industries Inc., a diversified commodity and specialty chemical manufacturer. He began his career at LaRoche as the chief financial officer.

Abbott Laboratories has received the 2001 Illinois **Governor's Pollution Prevention Award for Continuous Improvement** for its achievements in a healthy and safe environment. Abbott is the only healthcare company to have received the Governor's award five times in the history of the awards.

Inside the Community …

The Pan American Health and Education Foundation, a U.S.-based non-profit partner of the Pan American Health Organization (PAHO) presented **Dr. Ruy Laurenti** the **Abraham Horwitz Award** for his outstanding contribution to improve health in the Americas. Dr. Laurenti, a Brazilian professor of the School of Public Health of the University of Sao Paulo, Brazil, received the prestigious Award from Dr. Enrique Figueroa, Trustee of the Foundation, in an official ceremony in Washington, DC. The Abraham Horwitz Award is intended to stimulate excellence and leadership in health among persons who work in the Americas and who produce ideas and work primarily of regional significance. The Award is a tribute to Dr. Abraham Horwitz, a Chilean doctor who served as the director of PAHO for four terms and the President of the Foundation for 25 years.

U.S. Department of Health and Human Services (HHS) Secretary Tommy. G. Thompson today named **Donald A. Henderson, MD,** to serve as director of a newly created Office of Public Health Preparedness, which will coordinate national response to public heath emergencies. Dr. Henderson was the founding director of the Center for Civilian Biodefense Studies at the Johns Hopkins Bloomberg School of Public Health. In his new position, he will work with all agencies within the department to enhance the response to the anthrax attacks, as well as many possible incidents in the future. Secretary Thompson also announced that **Phillip Russell,** a retired U.S. Army major general, who was the director of the Army's Medical Research Institute of Infectious Diseases, will join the department as a special advisory on vaccine development and production.

The National Hemophilia Foundation (NHF) has appointed **Glenn Mones** as its new Director of Communications effective December 3, 2001. Mr. Mones was formerly Director of Media Relations at Planned Parenthood Federation of America Inc. where he directed media efforts and supported communications for over 150 affiliates. Additionally, the NHF also appointed **Cheryl A. Hayden** as its new Director of Government Relations and Blood Safety, effective December 3, 2001. Ms. Hayden was formerly the Assistant Director of Government Relations at the American Academy of Dermatology.

As part of its campaign to find the cures for bleeding disorders, the National Hemophilia Foundation has awarded its first-ever **Laboratory Grant** of $163,018 to **Steve S. Sommer, MD, PhD,** Director of the Molecular Genetics and Molecular Diagnostics at the Beckman Research Institute of the City of Hope in Duarte, California. **Hengjun Chao, MD,** of the University of North Carolina, Chapel Hill, was given the **NFH Career Development Award.** The **Judith Graham Pool Postdoctoral Research Fellowships** were awarded to **Anja Ehrhardt, PhD,** of Stanford University; **Peter Vincent Jenkins, PhD,** of The University of Rochester Medical School; and **Bin Zhang, PhD,** of the University of Michigan medical School.

Mary Pierce, AlphaNet Coordinator for Ohio and Kentucky, carried the Olympic Torch in Falls Church, Virginia, in late December as part of the Salt Lake 2002 Olympic Torch Relay. Ms. Pierce was invited by the American Lung Association to represent them in the Olympic Torch Relay. Ms. Pierce received a double lung transplant in 1993, won a Gold medal cycling at the World Transplant Games in 1995, and won a Gold Medical in race walking at the U.S. Transplant Games in 1996. Ms. Pierce founded Team Alpha-1, a bicycle team whose mission is to promote early detection of Alpha-1 and organ donation.

The Board of Directors of the National Hemophilia Foundation (NHF) announced that Chief Executive Officer, **Stephen E. Bajardi** resigned from the organization, effective Friday, November 30, 2001. **Ingrid Montecino,** current Deputy Director of NHF, will assume the responsibility of Acting Executive Director.

Tony R. Morgan, center director of Alpha Therapeutic Corporation, Jacksonville, Florida, recently achieved the 10-year PED designation, Plasmapheresis Establishment Director. The PED is an ABRA certification program which recognizes plasma collection facility management personnel who demonstrate proficiency in knowledge of the rules and regulations governing the Source Plasma industry, and who promote sound management skills.

James F. Crispen, MD, retires from Sera-Tec Biologicals after serving as its Medical Director since 1969. See the article on page 16 for a profile of Dr. Crispen and his contributions to the plasma industry.

Prof Rainer Seitz from Germany's Paul-Erlich Institut was appointed as the new chairperson of the Group of Experts No 6B (Human blood and blood products) of the European Pharmacopoeia at the European Department for the Quality of Medicines (EDQM).

The American Red Cross has named **Harold Decker** as its interim chief executive officer, after Bernadine Healy announced that she was stepping down as CEO of the organization. Mr. Decker served as General Counsel of the ARC. ●

Calendar of Meetings & Events

Upcoming events and meetings of interest to our members and stakeholders. To submit a meeting or event to* THE SOURCE*, send it to: Editor,* THE SOURCE*, PPTA, 147 Old Solomons Island Rd., Annapolis, MD. 21401 or email to lschulte@pptaglobal.org:

In light of recent world events, it is best to check with each meeting group prior to making travel arrangements to confirm that details of the event haven't changed.

January 21 – 22, 2002: *World Federation of Hemophilia Global Forum,* Montreal, Canada. (Rescheduled from September).

January 31 – February 1, 2002: *Advisory Committee on Blood Safety and Availability, Health and Human Services,* Washington, DC. Contact: Stephen Nightingale, MD, Executive Secretary. 202.690.5560.

February 4 – 7, 2002: *Cambridge Healthtech Institute "Blood Product Safety and TSEs,"* Marriott, Washington, DC. Contact Elizabeth Lamb, Conference Director, CHI. Email: elamb@healthtech.com.

February 21 – 22, 2002: *IPT "Understanding Drug Submission Procedures in Japan to Achieve Faster Approval,"* London, UK.

February 23 – 27, 2002: *America's Blood Centers Annual Meeting,* Dallas, TX. Members only. Contact ABC at 202.393.5725.

March 14 – 15, 2002: *Blood Products Advisory Committee Meeting,* FDA, Washington, DC area. Contact Linda Smallwood, 301.827.3514.

March 20 – 21, 2001: *International Plasma Derivatives Congress,* Rome, Italy. Rescheduled from October. Sponsored by PPTA/EPFA.

April 15 – 18, 2002: *Fourth Annual BSP2002,* Biological Safety and Production, Vienna, VA. Contact IBC USA Conference, 508.616.5550.

April 17 – 19, 2002: *PPTA Workshop on Comparability,* Rockville, MD.

May 2 – 3, 2002: *Advisory Committee on Blood Safety and Availability, Health and Human Services,* Washington, DC. Contact Stephen Nightingale, 202.690.5560.

May 19 – 24, 2002: *XXV International Congress of the World Federation of Hemophilia,* Seville, Spain.

June 10 – 12, 2002: ***PPTA Plasma Forum,* Marriott Crystal Gateway Hotel, Crystal City, VA.**

June 13 – 14, 2002: *Blood Products Advisory Committee Meeting,* FDA, Washington,DC area. Contact Linda Smallwood, 301.827.3514.

June 26 – 27, 2002: *TSE Advisory Committee,* FDA. Washington, DC area. Contact William Freas or Sheila Langford. 301.827.0314.

September 12 – 13, 2002: *Blood Products Advisory Committee Meeting,* FDA, Washington DC Area.

October 17 – 18, 2002: *TSE Advisory Committee,* FDA.

October 26 – 30, 2002: *American Association of Blood Banks Meeting,* Orlando, FL. Contact AABB Meeting Services. 301.907.6977.

October 31 – November 2, 2002: *National Hemophilia Foundation 54th Annual Meeting,* Orlando, FL. Contact: 800.424.2634.

December 12 – 13, 2002: *Blood Products Advisory Committee Meeting.*

December 13 – 14, 2002: *Blood Product Advisory Committee Meeting,* Bethesda, MD.

June 9 – 11, 2003: *PPTA Plasma Forum,* Baltimore, MD.

INDUSTRY ABBREVIATIONS

APC	**Ambulatory Payment Classifications**
AWP	**Average Wholesale Price**
BPWG	**Blood Products Working Group**
BSE	**Bovine Spongiform Encephalopathy**
CPMP	**Committee for Proprietary Medicinal Products**
cSPC	**Core Summary of Product Characteristics**
DG	**Director General**
EDQM	**European Directorate for the Quality of Medicines**
EMEA	**European Medicines Evaluation Agency**
EP	**European Parliament**
EPCC	**European Plasma Collection Committee**
EPFA	**European Plasma Fractionation Association**
FDA	**US Food and Drug Administration**
IQPP	**International Quality Plasma Program**

Coming... in February

Interview with Trevor Barrowcliffe

What is EPCC?

Profile on the New PPTA Chair

the SOURCE

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